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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906-AB00

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

AGENCY: Office of the Secretary, HHS.

ACTION: Notice of public hearing.

SUMMARY: This document announces a public hearing to receive information and views on the Notice of Proposed Rulemaking (NPRM) entitled “National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table.”

DATES: The public hearing will be held on January 13, 2014, from 10:30 a.m. – 12 p.m. (EDT).

ADDRESSES: The public hearing will be held in Conference Room 10-65 in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Dr. Vito Caserta, Acting Director, Division of Vaccine Injury Compensation, at 855-266-2427 or by email vcaserta@hrsa.gov.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986, Title III of Public Law 99-660, as amended (42 U.S.C. 300aa-10 et seq.), established the National Vaccine Injury Compensation Program (VICP) for persons found to be injured by vaccines. The Secretary has taken the necessary initial steps to propose to amend the Vaccine Injury Table to add intussusception as an injury associated with rotavirus vaccines.

The NPRM was published in the Federal Register, July 24, 2013: 78 FR 44512. The public comment period closes January 21, 2014.

A public hearing will be held during the 180-day public comment period. This hearing is to provide an open forum for the presentation of information and views concerning all aspects of the NPRM by interested persons.

In preparing a final regulation, the Secretary will consider the administrative record of this hearing along with all other written comments received during the comment period specified in the NPRM. Individuals or representatives of interested organizations are invited to participate in the public hearing in accord with the schedule and procedures set forth below.

The hearing will be held on January 13, 2014, beginning at 10:30 a.m. and ending at 12 p.m. (EDT) in Conference Room 10-65 in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Upon entering the Parklawn Building, persons who wish to attend the hearing will be required to call Ms. Andrea Herzog at (301) 443-6634 to be escorted to Conference Room 10-65.

The public can also join the meeting via audio conference call:

Audio Conference Call: Dial 800-369-3104 and provide the following information:

Leaders Name: Dr. Vito Caserta

Password: HRSA

The presiding officer representing the Secretary, HHS will be Dr. Vito Caserta, Acting Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau (HSB), Health Resources and Services Administration.

Persons who wish to participate are requested to file a notice of participation with the Department of Health and Human Services (HHS) on or before January 9, 2014. The notice should be mailed to the Division of Vaccine Injury Compensation, HSB, Room 11C-26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mailed to aherzog@hrsa.gov. To ensure timely handling, any outer envelope or the subject line of an e-mail should be clearly marked "VICP NPRM Hearing." The notice of participation should contain the interested person's name, address, e-mail address, telephone number, any business or organizational affiliation of the person desiring to make a presentation, a brief summary of the presentation, and the approximate time requested for the presentation. Groups that have similar interests should consolidate their comments as part of one presentation. Time available for the hearing will be allocated among the persons who properly file notices of participation. If time permits, interested parties attending the hearing who did not submit notice of participation in advance will be allowed to make an oral presentation at the conclusion of the hearing.

Persons who find that there is insufficient time to submit the required information in writing may give oral notice of participation by calling Andrea Herzog, Division of Vaccine Injury Compensation, at (301) 443-6634, no later than January 9, 2014.

After reviewing the notices of participation and accompanying information, HHS will schedule each appearance and notify each participant by mail, e-mail, or telephone of the time allotted to the person(s) and the approximate time the person's oral presentation is scheduled to begin.

Written comments and transcripts of the hearing will be made available for public inspection as soon as they have been prepared, on weekdays (federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m. (EDT) at the Division of Vaccine Injury Compensation, Room 11C-26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Dated: January 6, 2014

Kathleen Sebelius

Secretary

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